BOARD OF REGISTRATION IN PHARMACY MINUTES: PHARMACY BOARD MEETING TUESDAY, SEPTEMBER 14, 2004 MASSACHUSETTS COLLEGE OF PHARMACY AND HEALTH SCIENCES 179 LONGWOOD AVENUE, 2nd FLOOR, WHITE HALL BOSTON, MASSACHUSETTS

Present: James T. DeVita, R.Ph., Pres., Karen Ryle, R.Ph., M.S., Secy, Harold Sparr, R.Ph., M.S., (arrived late) Marilyn Barron, MSW, Public Member, George Cayer, R.Ph., Bill Gouveia, R.Ph., M.S., Joel Berman, R.Ph., Steven Budish and Sophia Pasedis, R.Ph. Absent: Donald Accetta, M.D., M.Ph.

Staff present: Charles R. Young, R.Ph., Exec. Dir., Susan Manning, J.D., Administrative Counsel, Leo McKenna, R.Ph., Pharm.D., CQI Surveyor, Leslie Doyle, R.Ph., Healthcare Supervisor, James Emery, Healthcare Investigator, and Samuel Penta, R.Ph. Healthcare Investigator.

- 1. 9:30 a.m. Meeting was called to order by President DeVita who expressed appreciation to President Chares Monahan, faculty and staff. President DeVita also welcomed the students and thanked them for finding the time to learn more about the operations of the Board.
- 9:30 a.m. MCPHS
 Michelle Kalis, Dean and Chair of the Department of Pharmacy
 welcomed the Board and expressed congratulations to newly appointed
 Board members George Cayer, Sophia Pasedis, Joel Berman and Steve
 Budish.
- 3. 9:40 a.m. 10:00 a.m. Introduction of Board Members and Staff Each Board Member introduced themselves and gave a brief review of their professional careers.

In addition, the Board welcomes new Investigator, Samuel J. Penta, R.Ph. and Quality Assurance Surveyor, Leo McKenna, R.Ph., Pharm.D. Mr McKenna gave a brief review of his professional career and vision for the CQI position.

Board Executive Director introduced himself to the students and spoke about his 18 year career with the Board and the positive impact of the recent move of the health boards to the Department of Public Health. He also recognized Donna Horn and Dan Sullivan for their personal contributions to the Board during his tenure as director.

- 4. 10:00. a.m. Contemporary Issues in Pharmacy
 President Jim DeVita conducted a PowerPoint presentation entitled
 "Contemporary Pharmacy Issues", related to regulating in systems where
 establishing accountability in a non-punitive environment presents
 opportunities, yet challenges. His presentation covered continuing quality
 improvement, risk management and reasons for root cause analysis to
 identify, analyze and develop action plans to prevent recurrence in health
 systems regulated by the Board. He also described to the students the
 importance of recognizing that the scope of responsibility extends to
 FDA, boards, health care practitioners and the systems of drug delivery.
 His talk was an excellent gateway into the next portion of the agenda.
- 5. 10:30 a.m. 11:00 a.m. MCPME
 Paula Griswold, Executive Director of the Massachusetts Coalition for the Prevention of Medical Errors (MCPME) conducted a PowerPoint presentation about current initiatives of the Coalition and the role of the Coalition as advisor to the Betsy Lehman Center for Patient Safety. She pointed out that two recent initiatives of the Coalition, Reconciliation of Medication and Reporting of Critical Test Results, were adopted by the Joint Commission on Accreditation of Healthcare Organizations. She also applauded the Board's patient safety initiatives and indicated a willingness to continue working with the Board and its staff in the Coalition's ambulatory practice initiatives.
- 6. 11:00 a.m. Jean Pontikas, Director of the Division of Health Professions Licensure (DHPL), Center for Health Quality and Control, presented outgoing Board members, Donna Horn and Daniel Sullivan with plaques, one signed by the Governor and one signed by the Commissioner, recognizing their years of volunteer service to the Commonwealth and to the Board, and to consumers the Board serves.

- 7. 11:30 a.m. The Board, staff and invited were invited to visit the Pharmacy Practice Laboratory (PPL) where Professor Susan Jacobsen and Dean Joseph Calomo gave an overview about contemporary changes made to the labs processes. The PPL is now set up to function much like a pharmacy with underclassmen acting as technicians and 5th and 6th year students acting as dispensers and providers of pharmaceutical care.
- 8. 12:00 p.m. 1:30 p.m. Board members, staff and invited guests were invited to the Brant House, a residence of the President of the College. President Monahan welcomed the members and gave a historical sketch of the college and his role as former executive director of the Board. Board President Jim DeVita once again formally thanked the President, faculty and staff for giving the Board an opportunity to reach out to the students, and for providing the facilities, audiovisual and support services.
- 9. 1:30 p.m. 1:50 p.m.

Electronic Data Transmission Grant Carrow, Ph.D., Deputy Director, Quality Assurance and Control, and Director of the Drug Control Program, met with the Board as follow-up to their presentation held at the last Board meeting. Doctor Carrow explained that the Drug Control Program was sensitive to the Board's comments and had proposed some accommodating language in the final draft regulations, soon to be distributed and considered at a public hearing.

Board President DeVita expressed concern about patient needs and possible risk in denying a patient without positive identification. Doctor Carrow replied that the proposed amended regulations are intended to be a law enforcement tool, and, by requiring someone who picks up a Schedule II prescription to provide an address and sign the back of the purported prescription, strikes a balance.

Board member George Cayer asked what other states have done about requiring positive identification. Doctor Carrow explained that five states currently require positive identification prior to dispensing a Schedule II Controlled Substance; Idaho, Kentucky, Texas, Nevada and Utah. He also added that of all the states requiring positive identification, Massachusetts is the only one, under existing regulations, offering a choice.

Board member Karen Ryle expressed concern about the proposal which would require a person, without identification, to sign the back of a prescription, prior to dispensing. She indicated that is may slow down and disrupt the dispensing system. Karen recommended, and all agreed that effective education prior to the regulation being released may be effective in educating the regulated community about the value of obtaining positive identification.

- 10. 1:50 p.m. 2:30 p.m. New Business for discussion
- a) Review of Minutes from a previous meeting June 22, 2004 Motion to adopt by Harold Sparr, Seconded by Steve Budish, motion carried.
- b) In the matter of PH-99-100 / Registrant, Robert J. Reynolds, R.Ph. (Lic. No. 19953). Request for removal of Probation. Previous to the discussion the Board received a copy of Mr. Reynold's release from MPRS. According to Tim McCarthy, MPRS Coodinator, pharmacist Reynolds was "an exemplary participant". Motion to approve by Harold Sparr, seconded by Sophia Pasedis, motions carrried.
- c) 2005 Board of Pharmacy Meeting Dates: amended as requested on August 10, 2004. No comments by Board, therefore schedule finalized.
- d) Federation of State Medical Boards (FSMB) Educational Workshop Series 2004 & 2005 proposed workshop scholarship grants dates for two (2) Board representatives. Harold Sparr and President DeVita volunteered to attend and represent the Board. A motion was made by George Cayer, seconded by Karen Ryle to approve, and the motion carried. President DeVita requested that the Board executive director notify FSMB as soon as possible.
- e) Click Pharmacy request for advisory opinion regarding licensure. Click Pharmacy is an out of state, VIPPS certified entity serving as a conduit between consumers and select pharmacies in the Click Pharmacy network. The company was seeking an opinion from the Board about the requirement for licensure. A motion was made by Harold Sparr, seconded by Joel Berman to notify Click pharmacy that licensing is not required. Board member Sophia Pasedis recommended, and Board approved that it should be emphacized that as an out of state pharmacy, the Board lacks jurisdiction, therefore no licensing required at this time.
- f) Angelique Reitmeier request for advisory opinion regarding internship (follow up to information requested by the Board during the July 13, 2004 meeting). Ms. Reitmeier is seeking internship credit for hours worked at the Drug Utilization Board at University of Massachusetts.

- After discussion, a motion to approve the hours was made by Harold Sparr, seconded by Joel Berman, motion carried. The hours would be acceptable as part of the 400 hours as a "demonstration project".
- g) Discussion related to the need to cancel the October 19, 2004 Board meeting (District I Meeting scheduled for October 14 16, 2004). Associate Director Coffey cites closeness to NABP District One Conference. According to executive Director, cases scheduled for investigative conferences are current. Following discussion, a motion was made by Harold Sparr, seconded by Karen Ryle tocancel the meeting, but President DeVita requested that investigators conduct a file review as soon as possible.
- 11. 2:30 p.m. 3:00 p.m. (Handout B) New Retail Pharmacy Application- In the matter of Greater Lawrence Community Health Center Pharmacy, 34 Haverhill Street, Lawrence, MA. The proposed Manager of Record is Viola Amy MacDougall, R.Ph., License No. 21301 (Registrant).

Registrant attended and was accompanied by Daniel Geribo, pharmacy consultant and Robert Ingola, CFO.

The Board requested that Registrant submit continuing education credit for 2002 and 2003, which were found to be compliant.

According to Registrant, the proposal is to establish a 340B pharmacy offering retail pharmacy services to poor, indigent, free care, Medicaid and cash patients, with no restrictions or requests for waivers. The service would also extend to 4 clinics wholly owned by the non-proft 340B corporation. Registrant expressed hope to improve medication compliance by having pharmacy services available at the clinic.

According to CFO Ingola, none of the directors or owners have prescriptive privileges.

The board was concerned about the schedule of hours of opening/closing and according to Ms. MacDougall, the hours had been revised and the pharmacy would only be open Monday-Friday. After discussion, the Registrant offered to have a pharmacist placed on call list for answering service.

Motion to approve the application made by William Gouveia, seconded by Sophia Pasedis, contigent upon receiving final approval by the DPH, Health Quality Division and a final inspection report approved by the Board's investigators. The motion carried.

12. 3:00 p.m.- Board Member George Cayer spoke about the issues involving long term care pharmacy practice. According to Board Member Cayer, long term care pharmacy is more of a hybrid practice between institutional pharmacy and retail pharmacy practice. He gave the students a personal perspective about the evolution of today's long term care pharmacy practice from the 1970's to present and discussed the goals of the Long Term Care Pharmacy Alliance founded in 2001.

He further discussed the challenges and opportunities of automation in long term care and described his continued efforts to organize the Board's Long Term Care Advisory Committee, approved at the August 10, 2004 meeting. The committee's progress will be reported at each business meeting of the Board and included in President DeVita's strategic action plan.

13. Adjourn - A motion was made to adjourn by Harold Sparr, seconded by Joel Berman, the motion carried and the Board adjourned at 3:30 p.m.

Respectfully submitted by:

Executive Director Dat

Reviewed by counsel: September 22, 2004

Draft approved: September 22, 2004

Board approved: October 12, 2004 as amended